Docket No. 60687 (46865)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Kusk, Phillip	
SERIAL NO.:	09/889,491	GROUP NO.: 1634
FILED:	February 5, 2002	EXAMINER: Switzer, Juliet C.
FOR:	GENETIC PREDISPOS	SITION
Mail Stop Non-Fe Commissioner for P. O. Box 1450 Alexandria, VA	Patents	
	CERTIFICA.	TE OF MAJLING
I hereby ce	rtify that this paper (along w	rith any paper referred to as being attached or
enclosed) is being	deposited with the United S	lates Postal Service as Express Mail No.
	in an envelope addre	essed to the: Commissioner for Patents, P. O. Box
1450, Alexandria,	VA 22313-1450 on	in the state of th
		
	В	y:Patricia A. Barnes
		Patricia A. Barnes
Sir:		
DE	CLARATION OF PHILL	IP KUSK UNDER 37 CFR 1.132
I, Phillip Kusk, deci		J. J
2, 2 mmp Rusk, dec	are as follows:	
1. I hav	e read the above-identified a	application (hereafter "subject application") of
2. I curr Copenhagen	ently hold the position of	Res. Sci at NoGene in

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- 3. As I understand it, the subject application discloses and claims, among other things, a method of assessing an individual's predisposition to a selected calcification status which includes the step of determining the genotype of a promoter of the bone sialoprotein (BSPII) gene. More specifically, the method analyzes allelic variation in the promoter and relates the variation to the predisposition.
- 4. I reviewed the Patent Office Action ("Office Action") dated January 2, 2004 that issued in connection with the subject application. As I understand the Office Action, the patent Examiner rejected certain claims as indefinite for reciting certain accession numbers from the Genbank database. I am familiar with the contents and use of that database particularly as it relates to the BSPII gene and related sequences disclosed throughout my patent specification.
- 5. I have been asked to state the identity of sequences referred to by the following Genbank accession numbers: L24756, M55270, D14813, and AB008821. The accession numbers refer to specific sequences and are featured throughout my patent specification as well as pending claims 25-30. I have been further asked to state whether or not those sequences are identical to those available to me from the Genbank database at the time the above-referenced application was filed.
- 6. Attached as Appendix A is a list of the sequences referred to by the Genbank accession nos. L24756, M55270, D14813, and AB008821. The list shows, among other things, the chemical identity of each of the sequences including the length of each sequence and positions of each base pair.
- 7. Referring now to Appendix A, I state that each of the sequences shown as Genbank accession nos. L24756, M55270, D14813, and AB008821 was available to me as a Genbank record no later than January 18, 1999; the earliest priority date of the above-captioned application.

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- 8. I further state that the base pair positions of each the sequences shown in **Appendix A** as Genbank accession nos. I.24756, M55270, D14813, and AB008821 corresponds to the base pair positions referred to throughout my patent specification for the same accession number.
- 9. For instance, pending claim 25 features two sequences (SEQ ID Nos. 18 and 13) that occur about base pair 1496 of the BSPII gene promoter (Genbank accession number L24756). Those same sequences can be seen in about the same position in Appendix A as Genbank accession no. I.24756. Additionally, pending claim 28 features two sequences (SEQ ID Nos. 23 and 24) that occur at about base pair 163 of the gene having accession number AB008821. Those same sequences can be seen in about the same position in Appendix A as Genbank accession number AB008821.
- 10. I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date; .

Phillip Kusk

Doc. 451679

APPENDIX A - Pg. 1 of 11

BSPII

```
HSDNSPOl standard; genomic DNA; HUM; 2415 EP.
 AC
      L24756; L06823;
 хx
 sv
      L24756.1
XX
DT
      13-JAN-1994 (Rol. 38, Created)
\mathbf{p}\mathbf{T}
      30-JUN-1999 (Rel. 60, Last updated, Version 3)
     Human bone staloprotein (BNSP) gene, exon 1.
XX
KW
      sialoprotein.
ХX
03
     Homo gapieos (human)
     Eukaryota; Motazoa: Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia;
oc
oc
     Eutheria; Primates; Catarrhini; Hominidae; Homo.
хx
RN
RР
     MEDLINE; 94340202.
RХ
RX
     PUBMED; 8061918.
     Kim R.H., Shapiro H.S., Li J.J., Wrang J.L., Sodek J.,
RΛ
     "Characterization of the human bone sialoprotein (BSP) gene and its
RT
RT
     promoter sequence";
КL
     Matrix Biol. 14(1):31-40(1994).
ХX
     Key
                      Location/Qualifiers
FŢ
                      1..2415
FТ
                       /db_xref="taxon:9606"
FT
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FT
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FT
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xx
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taaaaceata aaaaceetag aagaaacet aggeattace atteaggaca taaggeatggg
                                                                                   60
                                                                                  120
     cauggoette atgletadaa caceaaaage aaggeaacaa aagacaaaat tgacaaatgg
     gatethatta aactanngag ettetgenen geaanngaaa etaccateag agtganengg
                                                                                  180
     caacctacaa aatgggagaa aattubegen acctactout ctgacaaagg getaatatee
                                                                                  240
                                                                                  300
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                                                                                  360
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     atgaaaaaat geteaccate actggeeate agagaaatge aaatcaaaaac cactatgaga
     baccatetes caccagttag satggcaate attamanagt caggmaness caggtgetgg
                                                                                  480
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                                                                                  500
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                                                                                  660
                                                                                  720
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                                                                                  780
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                                                                                  840
                                                                                  900
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                                                                                 1080
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                                                                                 1140
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                                                                                1200
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                                                                                1260
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                                                                                 1320
                                                                                1380
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                                                                                1440
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                                                                                1500
                                                                                15G0
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                                                                                1620
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                                                                                1680
    aaatattgat ggtteatetg eteettbeee teattattta gtttttettt ettttttag
                                                                                1740
                                                                                1800
    ctaaactaat graaaattat atctaatgac agcaagettt cetttettte gacatagtga
    accontrying authanges bittheaseg officeedon trythethe bitteethes
    aatocagtat attattatac atatteggag coccaactat teatesteat etanacette
                                                                                1920
                                                                                1980
    aattanatto cacoatgosa acotottiggo totugastos egittetigt tiaticaset
                                                                                2040
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APPENDIX A - Pg. 2 of 11

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gagectgtgt ettgaaaa egttgaagtt tgggggtttt etggtgaaaa teeaegttet 2100 gaeateaeet tggtegtaa agtgattgge tgttggaagg eaaagaagag tttatageea 2160 geaagageaa gtgaatgagt gagtgagagg geagaaggaat tacteaatet gtgeeatea 2220 etgeettgaa eetgetteet eaeteeagga etgeeagagg gtaagattta atagaacaac 2280 teeattatea taaaattaga eaeteeatag ttacaateet etgaaettta atagaaetaga teeattaaaa taattaaa gatgtaatt gatgtaaaa ggettaaaaa ttattatea ttaaaetgge 2400 aetteagatt teaaa
```

MGP

```
ID
       HEMGPA
                   standard; genomic DNA; HUM; 7734 BP.
 λC
       M55270; J05572;
 хx
 SV
       M55270.1
 XX
 \mathbf{pr}
       21-NOV-1990 (Rel. 25, Created)
       02-JUL-1999 (Rcl. 60, Last updated, Version 4)
 DE
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 ХX
 KW
       matrix Gla protein; vitamin K-dependent protein.
 XX
 03
      Homo sapiens (human)
 OC
       Eukaryota; Mctazoa; Chordata; Craniata; Vortebrata; Euteleostomi; Mammalia;
 ФC
      Butheria; Primates; Catarrhini; Hominidae; Homo.
 RP
       1-7734
 RX
      MEDLINE; 90368682.
 RX
      PUBMED; 2394711.
 RΛ
       Cancela L., Haieh C.L., Francke U., Price P.A.;
 RT
       "Molecular otructure, chromosome assignment, and promoter organization of
      the human matrix Gla protein gene";
      J. Biol. Chem. 265(25):15040-15048(1990).
 KN
      [3]
 RP
      1-7734
 RΑ
      Price P.A.;
 RT
 RL
      Submitted (20-NOV-1990) to the RMBL/GenBank/DDBJ databases.
 RL
      Department of Biology, University of California-San Diego, La Jolla, CA
DR
      GDB; 126860; MGP,
DR
      GOA; P08493.
DR
      SWISS-PROT; PO8493; MCP_HUMAN.
XX
FII
      Key
                       Location/Qualifiers
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FT
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PΥ
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FT
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FT
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APPENDIX A - Pg. 3 of 11

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                                           Number X07362). This difference is due to polymorphism in
the MOP gene, since it is now clear that EST sequences from
                                            some cDNA libraries predict a penultimate alanino while EST
 ŀΤ
                                            sequences from other libraries predict threonine
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 PT
           exon
 FT
                                           /number-2
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 ÍΤ
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         ggccoatate Egtattttto totactgtat ttccagcota gagttgacaa acagtagatg
         ctcagtacat ttgttggeta gatagataac ttgatggatg getggctgge tggctggetg
                                                                                                                                                          240
         300
                                                                                                                                                          360
                                                                                                                                                          420
         argittanaa actogeaate atateactgi eleatative igitaleact teigggagti
                                                                                                                                                          480
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        totototada tetrototo tyantanon tetrototy tempyyana megetetoto aagigtotti catattate tunnatetaa tinguatetta gugitteaty tygteegte tegacaaga atcecaatta agaaaatyca ancingutyy cannatiaat tigteaaat tidagacagt attetycaat oteaacaat getatteeta accaaagaa ottitatte totyteeca tytetegeti tiaatatyte tegacatteta
                                                                                                                                                          540
                                                                                                                                                          720
                                                                                                                                                         780
         caactgoote egittitote tetomoteag tototaceta adacteacec agcadaceaa
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         attegraage elettereat treceetres ecettette tettetecta errecattot
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         tttettetgt erreteteng argagicaat eriggieett tetaatgeaa ageteeeate
        cerange created argageral criggreet terangera agerocal granders of the contact of
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                                                                                                                                                       1020
                                                                                                                                                       1080
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                                                                                                                                                       1260
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        angigingga titteaagtt tagtttetgg gagtytaana atanaanaac aattgtgatg
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                                                                                                                                                       1380
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                                                                                                                                                       1440
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                                                                                                                                                       1500
                                                                                                                                                       1560
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                                                                                                                                                      1680
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                                                                                                                                                      1800
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acygtottot trotgagatt ttorrtaaga ttttogGaca gataatctat ttottaggtt
                                                                                                                                                      1860
```

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2-2324333	a aacceege	C CABCAAGAC	'A AAAAMAAFC	(A samakasaa	A	210
ccaccaccy		c acacean.s	L EGADAGACA	た コトククコクククク	*	216
11300000000	a cederered	e ccaagagro	N GAGGEROPE	*********		222
adenererate	a adatatyyt	L CATTACETO	N EFABAGAAR	A ctaccters	A 964300L-3-	228
2~2~20~~		a cadactico	it gattgcaaa	A GARGGGGGA	a	
	~ ~~~~~~~~~~	u caavataan	c Manageare	A AACHOSSE	a ataata	234
-wwearaher	a Aracetees	g gcctgatgg	t otautoaaa	a cototoctt	7 37738AAALL	240
	a carecanta	a acuqtaaqt	a octationt	t accedantes		246
-33	g cacacacaca	e acaqcacct	a <i>deach</i> otae	c ttacetata	1 cotocosos	252
	r crarcasyr	- MUCCAACCA	t coadacaac	0 CCCCCA444	1 tananaa.	258
3-0-14-6-6	v woodbagging	. Caettteen	O CACLOSEAC	a ctacction		264
2	u guullaatyi	. cacaaaace	G GALOUGGAA	o transsava		270
Janecedus	v ccatggggc	i ccodatate	t ccatcccca	ľ gaareetkou	· •••••••	275
	, cocceagge	a aatacetaa	t tagtetagg	a trastament		282
teagecetad	regggaagate	cctaaatta	t nateactor	a ceducadar.	g trerectagas	288
agaugugge:	, audaterara	i aqaaqaana	ACREDERER D	M manatasti		294
***************************************		1 446996838	O AGDACACEA	O DOCKERALA	- ~! ~	3000
eccasaage	ctgcggtcae	ddccadawa	a atogateat	ggottergter	adottoctot	3060
>-333e-ccc	. 900000	. ucccccaaa	c acadontoo	C C22244444		3120
	, graacacaqt	Caggiccad	e agittaggga:	3 330400000		3180
444000000000	, 44990000900	. EGCEEGGGA:	n aagetecaal	- action:		3240
	. Lucuagucuc	. cccccacto	i tteeteenn	* atamataa.		3300
tasaaaccto	acagcettee	actaacatco	C Chinagaga	totatocat	ctggttetta	3360
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cgcagaaact	gatetetict	attaagtote	. Illialates	tabatata	gagtottatg	3660
caacttaaca	ggeaaacccq	Ctanataors	antetetet	. tabetaccc	ctcatattttc	3720
~9~~~9~	· vaccanaltc	CCSOCCCCC	こ のでみしゃんい チョト	· ++++	****	3780
acttragtat	caatgggtta	accotation	. traaaccook	tgcctttgag	accecteag	3840
		Cadecettre	, годидаегал			3900
-34409000	great caar	CCCBBBBBBB	, <u> </u>		A	3960
		COCCOGRAAA	1 23.3 3.1 FFFF		March 40 40 40 40 40 40 40 40 40 40 40 40 40	4020
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tteggetttg	atatoottto	agtteteter	Characters	ategtgecea	agaagaaaac	4440
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202000000	• • • • • • • • • • • • • • • • • • • •	unagacatea.	T ACCCCC F F F F F	~344bbb		4740
						4800
34-303000		accccaaacc	CCCCGAAAFFF	CF33F334		4860
						4920
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	AMMOR FOR STATE	9 LUGUEL GER	aucatomast	CF Paternance	* aabaa	5040
acatttoact	totttattca	aatcocttoo	attaaxonec	CtCttcttat	tagcaagega	5100
	aagn cacaca	acaddd addd	aaaaddddddd	CECEPPECO	2226F224	5160
	0	Latadaaaarr	OCCARRODA	~~ ~ h h h h h h h -		5220
	9994 t t t 369	CCECHOOCON	CALALLANA	*********		5280
	LLUGLACCAC	queaducted a	Cagargggass	250200000		5340
						5400
						5160
	COMMICEAGAG	CACACACACAC	EGGLCCCCCC	h		5520
						5590
						5540
						5700
						5760
						5820
		CHLCCCCCAAR	CLACLEARAS			5880
						5940
						6000
						<b>60</b> 60
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ccarttteto	tectamonto d		caagedatgt	gcasatacet ( gcasatacet (	rigication	6240
teageagaga	tqquaaarta :	accod	-eyyayaaat macchaa	gcasatacet ( acadaacete a	ratatecee	6300
gtcattitte .	Cogtotace	CBCACAFAR (	svyyccagta.	<b>acaa</b> aactte a gggaaacage (	*C9899a9t9	E360
tatacattat	ttctaartor -	tetttaaaa	anderadad£ i	gggaaacagc ( taaaagcaat a	ttttcatca	6420
caactgaatt :	Attagaaaar 1	atttoomen		chadagcaat a maggagaagg a	ttcagaaaa	6480
				**බබ්¶බ්මබ්මන්දීඨ ව	aaggagga	6540

## APPENDIX A - Pg. 5 of 11

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                                                                                                                                                                                                                                                                                       6660
                                                                                                                                                                                                                                                                                      6720
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 RL
      Shunsuke Yamamoto, Oita Medical University, Department of Fathology;
     Hasama-machi, Oita 879-55, Japan (Tel:0975-49-4411(ex.2690),
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     Shunsuke Yamamoto
     Department of Pathology
ĊC
     Oita Medical University
     1-1 Idaigaoka, Hasama-machi
Oita Gun, Oita 879-56
CC
CC
ÇÇ
     Japan
     Phone: 0975-49-4411 x2690
cc
     Fax:
             0975-49-4217
     Кеу
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## APPENDIX A - Pg. 6 of 11

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#### APPENDIX A - Pg. 7 of 11

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## APPENDIX A - Pg. 8 of 11

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- waratetea	L GOLOGICAA	c acacacaca	la taaktaaa	it accommond	98. Markar Later	144
wew age ye c	a agenteder	a victaacat	a ctaattest	. L L L L L L L L L L L L L L L L L L L		150
020000000	- AUCUACUEL	y catterace	O atoaumos	1C 330031355	·	156
	e marragement	H ULCAUCAGE	a acadageos	** 2117222		1630
Acc address	a Merececer	a gradecace	C EECLOROAC	:		1680
	y daladatica	C Cattconor	A FEFCATALA	(C) 33FFFF555		1740
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000000000		1 1000000000	g cccccccc	M 350006	~ ~~~	2040
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## APPENDIX A - Pg. 9 of 11

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Occountrace	tagattacoc		, accomacce	, aacacactaa	gaatattaaa	7440
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accasages	tagtgtagtt	tatoonetea	222222	taagaagttt	acatatgatg	8280
adaticeager.	##Stactth		Saccassato	caagaageee	cgcagaccty	8340
0445005050	******	alcagação ao ao	crgarggetc	tgactagege	teaagtetag	B4QQ
atteres	cerduacace	CULTCATECA	ttcalcoatt	cattoateca	ttcagcaaqa	8460
	accutacted	acqaccacco	- Batacaaret	++++~+ <i>~-++</i>		8520
	Laggicia	CAGATECGAR	ECECSASAS -	BARROR SALE	F F 4	8580
-22	acticaggae	taasataaac	COMMARCE	AAFFAFFFAA	*****	
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	무의 무현하실 다니라 다	Q C A G C C A C C A	MACCARACON	matmanaket .		8880
						8940
3	ar-nar-critical	auccagagag	LOGALARCOA	Propostate .		
コートコートケロしい	teattattet.	ccattratar	COPOSITION	FAGGGEGGE		9000
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Tantoaugee	703044555	cccccgaccg	agacagecar	addagagas i	gttatgaaac	9180
3-3KBC-B	Serdarcada.	GCGCCGAAAC	CCACACCCAC	BROOKS LACE		9240
,-,,		ucaacuauca	LECCGAEGEA	*********		9300
and of a complete	CGCGGGG	acadceatoa	acteoacaac	Carconnata (		9360
-3	무너 무리하다나라보다	aagataaaca	CCTGaaattt			
,	-cryaggcea	actaaaaaaa	<u>GADODAALAC</u>	ABELLOROSE P	PROGRESS.	9420
, , , , , , , , , , , , , , , , , , , ,	aauu Lyyttii	acadedaaac	DABAGAGAAA	APARTSEASE A		9480
ttattagtr	Odatotat	chattroant	organia and and and and and and and and and an	etaatgtgut u	eccccag	9540
ttagttton	ggccccater	aaanteeet~	Foodbards	იათოდყნებნ ნ	Aecegrega	9600
:Coattobat		and cooced		<b>g</b> ottcagggt t	atgictatg	9660
.ccarry, ar	uyaayaaatta	caaactatea.	Ctotattria	Ababbbabba b	tararas L	9720
wengamer	rangrayaag	CHBBCZABGC	actitioned	2014 *** ** * * * *	03 Manage	9780
· · · · · · · · · · · · · · · · · · ·	ACCULCATE	CCCGCCCCCC	aagttagtge -	3 F 3 F N S S	Charles	9840
	tyaasaaacc	ttttatata	Aatotaataa .	Daarttaata a	ENTANALE -	
tracttytt	ttcccacggt	totocagoaa	Etaptopaac	ataacettt t	tactacet:	9900
						9960

#### APPENDIX A - Pg. 10 of 11

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                                                                                             10320
      tgaggtcaac ttttetagat necacatatg agtgagatca tgeagtacte tteettetgt
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      aaaacatgca caaactutoc arctaacoog gaattamaar ccaguntaca taaggooctc
                                                                                            10440
                                                                                            10500
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      coaggatteg gggaaagaag gacattegta enetggtgag aactgtaaat tagtacagee actatgaaaa actgtutgga gacttetcaa aacaacaaaa atagaactac catattattt
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#### OPG

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 ХX
 SV
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      07-AUG-1998 (Rel. 56, Last updated, Version 2)
 DŢ
 DE
      Homo mapiens gene for osteoclastogenesis inhibitory factor, exon 1.
 хx
      enteoclastogenesis inhibitory factor.
 KW
 ХX
 20
      Homo sapiena (human)
 OC
      Eukaryota; Metažoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia;
 OÇ.
      Eucheria; Primates; Catarrhini; Hominidae; Homo.
 ХX
 RN
 RΡ
      1-1581
 KA
      Morinaga T.;
 RT
      Submitted (13-NOV-1997) to the EMBL/GenBank/DDBJ databases.
 RL
      Tomonori Morinaga, Snow Brand Milk Producto Co., Ltd., Research Institute
      of Life Science; 519 Shimo Ishibashi, Ishibashi-machi, Tochigi 329-0512,
 RL
      Japan (E-mail:fvbd7042@mb.infoweb.or.jp, Tel:0285-52-1331,
 RL
      Fax:0285-53-1314)
XX
RN
 Rr
      1-1681
 RX,
     MEDLINE; 98351569.
 RX
      PUBMED; 9688283.
     Morinaga T., Nakagawa N., Yasuda H., Tsuda E., Higashio K.,
RΛ
RT
      "Cloning and characterization of the gene encoding human
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RТ
     Eur. J. Biochem. 254(3):685-691(1998).
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DR
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FII
     Kev
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//

# APPENDIX A - Pg. 11 of 11

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****	gradaraatt	ccagaggaa	CCCGGGGAAGE	- Gtaateente	A & +	120
	. Accercanit	CCARCECCEA	gaccaddaaa		272727777	
		CCCCCCCC	tagettgagg	Chadhadaaa	G2GG2G44	180
aggotactoc	agaagtteag	cocotaogaa	actoccatac	COOREGEOR	ttgatgatgg	240
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accordana	craceactica	aggtttcaga	accognantg	gydddatcad	gcagccgggt	600
100010000	babbasat	regeograges	agaggacaaa	ggtetgggae	acactccgac	660
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3	racceda con	ruccauceact	agteceaart	CCCCCC Accc	<b>+</b>	780
A2220003333	CCGGGGGGGG	CCEU400000	GCGG8GACAG	Cancerert	Attactes.	940
		CHCLCCCCG	ggggacagac	ACCACCOCCC	GROOMEROOA	900
3-400000000		GGCCCCGGGGG	ccadcccton	<b>みろびひひととっっと</b>	Cobsesses	960
3-40405		CCCCGCCCaa	QUEECCEBAA	222222224	CC333441	1020
コーニクヘヨネベドロ	geennaugae	LUNCCADAGG	caggegatac	LECCEOPEAC.	COCCARAGE	1080
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totoccaaco	teccagegga	ссадсадава	gaagoeteca	ctcoctccct	Canada	1260
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a	-3	aaaccattat	antengaata	tgacatgata	gatttttcta	1680
						1681